Complete Summary

GUIDELINE TITLE

ACE inhibitor treatment in diabetic nephropathy.

BIBLIOGRAPHIC SOURCE(S)

Nicholls K. ACE inhibitor treatment in diabetic nephropathy. Nephrology 2006 Apr;11(S1):S79-91.

Nicholls K. ACE inhibitor treatment in diabetic nephropathy. Westmead NSW (Australia): CARI - Caring for Australasians with Renal Impairment; 2005 Sep. 17 p. [40 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Diabetic nephropathy

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Management
Treatment

CLINICAL SPECIALTY

Endocrinology
Family Practice
Internal Medicine
Nephrology
Pharmacology

INTENDED USERS

Pharmacists
Physicians

GUIDELINE OBJECTIVE(S)

To review the evidence that angiotensin converting enzyme (ACE) inhibitors in diabetes protect against the onset and progression of diabetic nephropathy

TARGET POPULATION

Patients with diabetic nephropathy:

- Patients with type 1 or type 2 diabetes mellitus complicated by microalbuminuria or overt nephropathy
- Hypertensive diabetics without albuminuria

INTERVENTIONS AND PRACTICES CONSIDERED

Angiotensin converting enzyme (ACE) inhibitor therapy

MAJOR OUTCOMES CONSIDERED

- Blood pressure
- Mean arterial pressure
- Cardiovascular events
- Renal function
    - Creatinine clearance
    - Albumin excretion rate (AER)
    - Glomerular filtration rate (GFR)
- Mortality

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Databases searched: The Cochrane Renal Group Specialised Register was searched for randomised controlled trials (RCTs) relating to the prevention of progression of kidney disease in people with diabetes mellitus type 1 and type 2.

Specific interventions included antihypertensive therapies, Angiotensin converting enzyme (ACE) inhibitors, Angiotensin II antagonists, calcium channel blockers, dietary protein restriction and glucose control, and interventions to control hypercholesterolemia and hyperlipidemia.

Date of search: 16 December 2003.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

Level I: Evidence obtained from a systematic review of all relevant randomized controlled trials (RCTs)

Level II: Evidence obtained from at least one properly designed RCT

Level III: Evidence obtained from well-designed pseudo-randomized controlled trials (alternate allocation or some other method); comparative studies with concurrent controls and allocation not randomized, cohort studies, case-control studies, interrupted time series with a control group; comparative studies with historical control, two or more single arm studies, interrupted time series without a parallel control group

Level IV: Evidence obtained from case series, either post-test or pretest/post-test

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Comparison with Guidelines from Other Groups
Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Recommendations of Others. Recommendations regarding angiotensin converting enzyme (ACE) inhibitor treatment in diabetic nephropathy from the following groups were discussed: Kidney Disease Outcomes Quality Initiative, United Kingdom Renal Association, Canadian Society of Nephrology, The Seventh Report of the Joint National Committee on the Prevention, Detection, Evaluation, and Treatment of High Blood Pressure, American Diabetic Association, American Diabetes Association, and Canadian Diabetes Association.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions for the levels of evidence (I–IV) can be found at the end of the "Major Recommendations" field.

Guidelines

a. All patients with type 1 or type 2 diabetes mellitus complicated by microalbuminuria or overt nephropathy should be treated with an angiotensin converting enzyme inhibitor (ACEI), independent of blood pressure and Glomerular filtration rate (GFR). (*Level I evidence*, greater for type 1 than type 2). There is no evidence that any specific ACEI offers any advantage over the class effect.
b. Hypertensive diabetics without albuminuria should be treated with ACEI as first-line antihypertensive therapy. (*Level I evidence*)
c. There is currently insufficient evidence to recommend universal ACEI treatment for all diabetic patients with normal blood pressure (BP) and albumin excretion rate (AER).

Suggestions for Clinical Care

(Suggestions are based on Level III and IV sources)

- A strong association between acute increases (up to 30%) in serum creatinine on initiation of ACEI treatment, stabilizing within the first 2 months of therapy, and long-term preservation of renal function is shown in one meta-analysis. ACEI therapy should be withdrawn only if creatinine increases > 30% above baseline within the first 2 months of therapy.
- Use of angiotensin converting enzyme (ACE) inhibitors may exacerbate hyperkalaemia in patients with kidney failure and/or hyporeninaemic hypoaldosteronism.

Definitions:

Levels of Evidence

Level I: Evidence obtained from a systematic review of all relevant randomized controlled trials (RCTs)

Level II: Evidence obtained from at least one properly designed RCT

Level III: Evidence obtained from well-designed pseudo-randomized controlled trials (alternate allocation or some other method); comparative studies with concurrent controls and allocation not randomized, cohort studies, case-control studies, interrupted time series with a control group; comparative studies with historical control, two or more single arm studies, interrupted time series without a parallel control group

Level IV: Evidence obtained from case series, either post-test or pretest/post-test

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of angiotensin converting enzyme (ACE) inhibitors in patients with diabetic nephropathy

POTENTIAL HARMS

- There is a strong association between acute increases (up to 30%) in serum creatinine on initiation of angiotensin converting enzyme inhibitor (ACEI) treatment, stabilizing within the first 2 months of therapy
- Use of ACEIs may exacerbate hyperkalaemia in patients with kidney failure and/or hyporeninaemic hypoaldosteronism

CONTRAINDICATIONS

CONTRAINDICATIONS

Angiotensin converting enzyme inhibitor therapy should be withdrawn only if creatinine increases > 30% above baseline within the first 2 months of therapy.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2005 Sep

GUIDELINE DEVELOPER(S)

Caring for Australasians with Renal Impairment - Disease Specific Society

SOURCE(S) OF FUNDING

Industry-sponsored funding administered through Kidney Health Australia

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

David Harris, Convenor (Westmead, New South Wales); Merlin Thomas (Prahran, Victoria); David Johnson (Woolloongabba, Queensland); Kathy Nicholls (Parkville, Victoria); Adrian Gillin (Camperdown, New South Wales)

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All guideline writers are required to fill out a declaration of conflict of interest.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Caring for Australasians with Renal Impairment (CARI) Web site.

Print copies: Available from Caring for Australasians with Renal Impairment, Locked Bag 4001, Centre for Kidney Research, Westmead NSW, Australia 2145

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- The CARI guidelines. A guide for writers. Caring for Australasians with Renal Impairment. 2008 Jul. 6 p.

Electronic copies: Available from the Caring for Australasians with Renal Impairment (CARI) Web site.

PATIENT RESOURCES

None available

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